

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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WEST VIRGINIA PIPE TRADES HEALTH  
& WELFARE FUND, EMPLOYEES'  
RETIREMENT SYSTEM OF THE STATE  
OF HAWAII, and UNION ASSET  
MANAGEMENT HOLDING AG,

Civil No. 13-1686 (JRT/FLN)

Plaintiffs,

v.

**MEMORANDUM  
OPINION AND ORDER  
ON MOTION FOR  
SUMMARY JUDGMENT**

MEDTRONIC, INC., WILLIAM A.  
HAWKINS, GARY L. ELLIS, RICHARD E.  
KUNTZ, JULIE BEARCROFT, RICHARD  
W. TREHARNE, and MARTIN YAHIRO,

Defendants.

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Shawn A. Williams and Christopher M. Wood, **ROBBINS GELLER  
RUDMAN & DOWD LLP**, One Montgomery Street, Suite 1800,  
San Francisco, CA 94104; Susannah R. Conn, **ROBBINS GELLER  
RUDMAN & DOWD LLP**, 655 West Broadway, Suite 1900, San Diego,  
CA 92101; Anne T. Regan, **ZIMMERMAN REED, PLLP**, 1100 IDS  
Center, 80 South Eighth Street, Minneapolis, MN 55402; and  
Christopher F. Moriarty, **MOTLEY RICE LLC**, 28 Bridgeside Boulevard,  
Mount Pleasant, SC 29464, for plaintiffs.

James K. Langdon, Theresa M. Bevilacqua, and Kristin K. Zinsmaster,  
**DORSEY & WHITNEY LLP**, 50 South Sixth Street, Suite 1500,  
Minneapolis, MN 55402, for defendants Medtronic, Inc., William A.  
Hawkins, Gary L. Ellis, Richard E. Kuntz, Julie Bearcroft, Richard W.  
Treharne, and Martin Yahiro.

Plaintiff retirement and investment funds (“plaintiffs”) bring this consolidated  
class action against Medtronic and several of its officers and employees (“Medtronic

Defendants” or “defendants”), alleging that the defendants made fraudulent statements, and engaged in a fraudulent scheme, in violation of federal securities laws. The case centers on the bone product INFUSE and alleges that the defendants made false statements about the safety and efficacy of INFUSE, which led to artificially high prices for Medtronic stock.

In a prior Order, the Court dismissed some of the plaintiffs’ false statement claims against various Medtronic Defendants and dismissed the plaintiffs’ scheme liability claims against several consultant defendants (“Consultant Defendants”). The Order rejected the motion to dismiss against the Medtronic Defendants as to one false-statement claim, the scheme liability claims, and related control person claims.

Now, with the benefit of additional record material, the Medtronic Defendants move for summary judgment, arguing that the plaintiffs’ claims are barred by the two-year statute of limitations found in 28 U.S.C. § 1658(b)(1) and the five-year statute of repose found in Section 1658(b)(2). Because the remaining false statement claim clearly falls outside the statute of limitations, the Court will dismiss that claim. Additionally, because publicly available information would have allowed the plaintiffs to plead plausible scheme liability claims prior to June 27, 2011, the Court will dismiss the plaintiffs’ remaining scheme liability claims. Finally, the Court will dismiss the control liability claims and deny as moot the defendants’ objections to a Magistrate Judge order regarding discovery issues.

## BACKGROUND<sup>1</sup>

### I. INFUSE AND THIS ACTION

INFUSE is the “trade name of rhBMP-2,” which is a bone morphogenetic protein (“BMP”) that induces the body to develop new bone tissue. (Consolidated Class Action Compl. (“Compl.”) ¶ 7, Nov. 4, 2013, Docket No. 28.) INFUSE is an alternative to grafting replacement bone tissue and was the first BMP to reach the market. (*Id.*) The FDA approved INFUSE in 2002 for what the plaintiffs allege are somewhat limited treatment purposes: treatment of degenerative disc disease, dental surgery, and certain shin fractures. (*Id.* ¶ 8.) INFUSE was never approved, however, “for any spinal fusion indication other than [the lower back] surgeries.” (*Id.*) INFUSE is a key part of Medtronic’s “spinal segment,” which generated more than \$3.5 billion in revenue in 2008, 2009, and 2010. (*Id.* ¶ 20.) Relevant to this case, Medtronic also sought FDA approval for AMPLIFY, a second-generation BMP. (*Id.* ¶¶ 22, 24.)

The lead plaintiffs in this case are several institutional investors: West Virginia Pipe Trades Health & Welfare Fund, Union Asset Management Holding AG, and Employees’ Retirement System of the State of Hawaii, all of which allege that they purchased Medtronic common stock during the Class Period<sup>2</sup> and were damaged by the

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<sup>1</sup> Because the plaintiffs’ allegations are set out at length in the Court’s prior Order in this case, *W. Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 57 F. Supp. 3d 950, 956-66 (D. Minn. 2014), the Court will only briefly recount the background of the case here, relying in part on the facts as set out in that Order.

<sup>2</sup> “Class Period” refers to the time period from September 8, 2010 to August 3, 2011. (Pls.’ Opp’n to Mot. for Summ. J. at 12 n.6, Apr. 7, 2015, Docket No. 101.)

conduct alleged in the complaint. (*Id.* ¶¶ 43-45.) They bring this action against Medtronic and several of its officers and employees, including: William Hawkins, former Chair of the Board of Directors and CEO, (*id.* ¶ 47); Gary Ellis, Chief Financial Officer, (*id.* ¶ 48); Richard Kuntz, Chief Scientific, Clinical and Regulatory Officer, (*id.* ¶ 49); Julie Bearcroft, Director of Technology Management in Medtronic's Biologics Marketing Department, (*id.* ¶ 50); Richard Treharne, Senior Vice President of Clinical and Regulatory Affairs, (*id.* ¶ 51); and Martin Yahiro, Medtronic Senior Director of Regulatory Affairs, (*id.* ¶ 52). The complaint also alleges violations by three consultants: Dr. Thomas Zdeblick, (*id.* ¶ 53); Dr. Kenneth Burkus, (*id.* ¶ 54); and Dr. Scott Boden, (*id.* ¶ 55).

The plaintiffs make two substantive claims in this case.<sup>3</sup> First, in Count I, they allege that the defendants made materially false statements during the Class Period in order to assure investors of the continued viability of INFUSE as a product and the prospect of AMPLIFY. (*Id.* ¶¶ 157-61.) The plaintiffs claim that these materially false statements artificially inflated Medtronic's stock price, which led investors to buy it, but that when the truth was revealed the value dropped. The complaint asserts these claims against Medtronic, Hawkins, Ellis, Kuntz, and Zdeblick. As discussed in more detail below, however, the Court's prior Order on the defendants' motions to dismiss rejected all false statement claims except as to Hawkins.

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<sup>3</sup> The plaintiffs' claim for control person liability, found in Count III, is derivative of the first two claims. (Compl. ¶¶ 166-70.)

The remaining false statement claim against Hawkins involves a February 22, 2011 conference call for analysts and investors that followed Medtronic's release of its 3Q11 financial results. (*Id.* ¶ 73.) On that call, Hawkins was asked about whether the FDA might delay its approval of AMPLIFY and whether any delay might negatively impact INFUSE sales. (*Id.*) The plaintiffs contend that Hawkins's responses "falsely suggested that approvability had not yet been determined, and . . . that even if there were a delay, it would not impact [Medtronic's] current business." (*Id.*) The plaintiffs contend that this statement was "knowingly materially false and misleading because . . . [Medtronic] had received a letter from the FDA before January 28, 2011, stating that AMPLIFY would not be approved." (*Id.* ¶ 74.) Later in the complaint, the plaintiffs explain that in Medtronic's 3Q11 10-Q, it "disclosed for the first time that . . . it had received a non-approval letter from the FDA concerning AMPLIFY: In the third quarter of fiscal year 2011, the FDA sent Medtronic a letter advising that they were not able to approve AMPLIFY at that time without additional information from Medtronic." (*Id.* ¶ 79.)

In Count II, asserted against all defendants,<sup>4</sup> the plaintiffs contend that before and during the Class Period, the defendants engaged in a scheme or course of conduct to manipulate the early clinical studies, which propelled INFUSE to success despite omitting many of INFUSE'S adverse effects. (*Id.* ¶¶ 162-65.) The plaintiffs allege that

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<sup>4</sup> As discussed in more detail below, however, the Court previously dismissed scheme liability claims against the Consultant Defendants, leaving only scheme liability claims against the Medtronic Defendants.

early INFUSE clinical studies revealed safety risks that threatened Medtronic’s goals for the product and, as a result, Medtronic “embarked on a scheme with physician investigators and authors to conceal the significant safety risks from the public and physician community.” (*Id.* ¶ 15; *see also id.* ¶ 163.) They allege that Medtronic did so by “forg[ing] relationships, including financial relationships, with physician authors who published research articles in respected medical journals and knowingly concealed in those original articles, or omitted altogether, known facts regarding INFUSE’s adverse side effects observed in clinical trials,” and that these research articles “overstated apparent disadvantages of alternate bone graft procedures . . . as opposed to treatment with INFUSE.” (*Id.* ¶ 16.) The plaintiffs also allege that Medtronic and the consulting physicians “knew but failed to disclose that Medtronic had paid millions of dollars to the same physician authors and that during the drafting process[] Medtronic employees heavily edited the articles and specifically excised true facts learned during clinical trials about the efficacy and side effects of INFUSE, which would have alerted the public and physicians using INFUSE about its harmful side effects and lack of clinical benefit.” (*Id.* ¶ 17.)

The critical dispute, at this stage, is which public disclosures made the market aware of the defendants’ alleged wrongdoing – especially the alleged scheme to manipulate early clinical studies.<sup>5</sup> The plaintiffs note that a May 25, 2011 article by

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<sup>5</sup> The parties also debate whether there is any dispute of material facts as to the defendants’ summary judgment arguments. Despite the plaintiffs’ protestations to the contrary, the Court finds that there is no dispute as to the statutes of limitations and repose issues.

(Footnote continued on next page.)

Eugene Carragee in *The Spine Journal* highlighted a link between INFUSE and retrograde ejaculation. (*Id.* ¶¶ 89-92.) This article prompted a June 21, 2011 letter to Medtronic from the United States Senate Finance Committee, expressing concerns that doctors conducting clinical trials had learned of medical complications associated with INFUSE but had not reported these concerns in medical literature. (*Id.* ¶ 101.) The letter noted that this issue was especially concerning given the lucrative financial ties many clinical investigators have to Medtronic. (*Id.*)

The plaintiffs point in particular, however, to *The Spine Journal*'s June 28, 2011 issue, which the journal devoted entirely to concerns regarding INFUSE. (*Id.* ¶ 103; *see also* Decl. of Christopher M. Wood ("Wood Decl."), Ex. 26 ("June 2011 Spine Journal Editorial"), Apr. 7, 2015, Docket No. 103.) The plaintiffs contend that, "[t]aken as a whole, the June 28, 2011 issue of *The Spine Journal* began to inform the market, for the first time, that the research supporting the safety and efficacy of INFUSE was not reliable." (Compl. ¶ 103.) That same day, Medtronic filed its FY11 Form 10-K, which included a statement about *The Spine Journal* articles and "conceded that the articles would have an impact on future sales." (*Id.* ¶¶ 112.) The plaintiffs contend that these disclosures led to a drop in Medtronic stock by \$.92 to close at \$38.09 on June 29, 2011, which was a one-day decline of nearly 3%. (*Id.* ¶ 113.) The stock dropped further in the

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(Footnote continued.)

Additional discovery beyond what the defendants have provided would not change the Court's ability to assess what information was publicly available to the plaintiffs regarding the defendants' alleged misconduct in the months and years leading up to the plaintiffs' filing of the complaint in this case.

subsequent week, falling from \$39.12 on July 1, 2011 to \$37.96 on July 5, 2011. (*Id.* ¶¶ 114-16.)

The plaintiffs also highlight the subsequent Staff Report of the Senate Finance Committee (“Senate Report”), which was issued in October 2012. (Wood Decl., Ex. 39 (“Senate Report”).) The Senate Report revealed a variety of findings, including that “Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic.” (Compl. ¶ 35.) The report also found that “Medtronic officials inserted language into studies that promoted InFuse as a better technique than taking a bone graft from the pelvic bone . . . by emphasizing the pain of the autograft technique.” (*Id.*)

In the defendants’ recounting of the background of this case, they highlight additional litigation and additional articles that they say would have given the plaintiffs sufficient notice to file a complaint much earlier than the June 2011 Spine Journal issue. In particular, they note that the Minneapolis Firefighters’ Relief Association filed an action against Medtronic in December 2008, in which it alleged that Medtronic had developed lucrative relationships with doctors and medical researchers to encourage them to publish articles that would recommend the use of INFUSE for off-label purposes. (*Minneapolis Firefighters’ Relief Assoc. v. Medtronic, Inc., et al.*, No. 08-6324, Consolidated Class Action Compl. (“*Minneapolis Firefighters* Compl.”), August 21, 2009, Docket No 68.) They also cite various academic and newspaper articles that they claim raised all of the allegations in the plaintiffs’ complaint, well before the June 2011

Spine Journal issue.<sup>6</sup> (*See* Decl. of Theresa M. Bevilacqua (“Bevilacqua Decl.”), Exs. 4-15, Mar. 17, 2015, Docket No. 97.) Specifically, the defendants claim that these academic and media articles have discussed, at some point, allegations that: (1) pro-INFUSE researchers were biased; (2) pro-INFUSE doctors received payments from Medtronic; (3) research on INFUSE overstated its benefits; (3) adverse events in INFUSE’s development and adverse effects of the product were hidden or ignored; and (4) Medtronic had an overarching goal of aggressively marketing and selling INFUSE, and thereby dominating the market. The Court will not recount the specifics of each of these articles at this point, but will instead refer to them as needed in its analysis below.

## II. MOTION TO DISMISS PROCEEDINGS

The plaintiffs filed their initial complaint on June 27, 2013, and submitted an amended complaint on November 4, 2013. All defendants moved to dismiss the plaintiffs’ complaint. As noted above, in its prior Order, the Court dismissed almost all

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<sup>6</sup> The plaintiffs have filed objections to the defendant’s submission of news articles and FDA materials and clinical studies. (Pls.’ Evidentiary Objs., Apr. 7, 2014, Docket No. 102.) The plaintiffs allege that all of the submitted materials are hearsay and that the FDA materials and clinical studies would introduce prejudice and confusion if not accompanied by expert testimony. The Court is not persuaded that it cannot rely on the materials submitted by the defendants at this stage. First, the defendants are not submitting the materials to “prove the truth of the matter asserted” within them. Fed. R. Evid. 801(c)(2). The defendants obviously do not seek to prove the truth of the allegations in the materials; they merely want to demonstrate that the allegations – true or not – contained in those materials are comprehensive enough to have allowed the plaintiffs to file their securities fraud complaint earlier. *See Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9<sup>th</sup> Cir. 2009) (“Courts may take judicial notice of publications introduced to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true.”). Second, the Court is confident it can mitigate any prejudice or confusion that might be generated by the FDA materials and clinical studies.

of the plaintiffs' false statement claims in Count I, except those allegedly made by Hawkins regarding the FDA's approval or lack thereof of AMPLIFY. *W. Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 57 F. Supp. 3d 950, 968-76, 985 (D. Minn. 2014) (*Medtronic*).

As for Count II – the scheme liability allegations – the Court concluded that the plaintiffs had sufficiently pled scheme liability against the Medtronic Defendants and denied their motion to dismiss. *Id.* at 980-83. The Medtronic Defendants did not present any statute of limitations defense. *Id.* at 980.

However, the Court granted the motion to dismiss scheme liability claims against the Consultant Defendants. *Id.* at 977-80. Under the relevant statutes of limitation and repose, in light of the fact that the complaint was filed on June 27, 2013, the plaintiffs “must not have discovered the ‘facts constituting the violation’ before **June 27, 2011**” in order to comply with the two-year statute of limitations. *Id.* at 978 (emphasis added) (quoting 28 U.S.C. § 1658(b)(1)). “[T]he last alleged violation must not have occurred before **June 27, 2008.**” *Id.* at 978 (emphasis added); 28 U.S.C. § 1658(b)(2). As for the statute of limitations, the Court found that the plaintiffs “brought this action within two years of its discovery of the facts constituting the violations it alleges, because it was not until at least the June 28, 2011 issue of The Spine Journal that Medtronic’s involvement in promulgating the early INFUSE studies and the physician consultants’ conflicts of interest were revealed.” *Id.* at 978. Under the five-year statute of repose, however, the Court concluded that “none of [the] alleged violations [against the Consultant Defendants] since June 2008 [met] the requisite pleading standards for the elements of a

claim for scheme or course of conduct liability under Rule 10b-5(a) or (c).” *Id.* at 979. As a result, the Court granted the motion to dismiss the Count II scheme claims against the Consultant Defendants. *Id.* at 980.

Finally, the Court did not dismiss the Count III control person liability claims. *Id.* at 984. Following this Court’s prior Order, the Medtronic Defendants filed this motion for summary judgment, premised on statute of limitations and statute of repose arguments. (Mot. for Summ. J., Jan. 12, 2015, Docket No. 88.)

## **DISCUSSION**

### **I. STANDARD OF REVIEW**

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

### **II. GOVERNING SECURITIES LAW**

Section 10(b) of the Exchange Act makes it unlawful for “any person . . . [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative

or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe.” 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements the provisions of section 10(b), *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 980 (8<sup>th</sup> Cir. 2012), which makes it unlawful to (a) “employ any device, scheme, or artifice to defraud,” (b) “make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading,” or (c) “engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,” in connection with the purchase or sale of any security, 17 C.F.R. § 240.10b-5.

The remaining claim under Count I against Hawkins alleges violations under subsection 10b-5(b), for untrue statements of material fact. There are six elements of a claim for material false statements under Rule 10b-5(b): (1) a material misrepresentation (or omission); (2) scienter, or intent to deceive, manipulate, or defraud; (3) a connection with the purchase or sale of a security; (4) reliance (sometimes referred to as “transaction causation”); (5) economic loss; and (6) “loss causation,” or a causal connection between the material misrepresentation and the loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005); *see also In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006 (9<sup>th</sup> Cir. 2005).

Count II alleges violations under subsections 10b-5(a) and (c) for a fraudulent scheme, act, or course of business. *See* 17 C.F.R. § 240.10b-5. Claims brought under Rules 10b-5(a) and (c) are generally referred to as “scheme liability” claims, and are distinct from claims under Rule 10b-5(b) because they are based on deceptive **conduct**

rather than deceptive **statements**. *See KV Pharm. Co.*, 679 F.3d at 986. To state a claim under Rule 10b-5(a) and (c) for scheme liability, “a plaintiff must allege that the defendant (1) committed a deceptive or manipulative act (2) with scienter, (3) that the act affected the market for securities or was otherwise in connection with their purchase or sale, and (4) that defendants’ actions caused the plaintiffs’ injuries.” *In re Parmalat Sec. Litig.*, 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006).

### III. STATUTE OF LIMITATIONS

28 U.S.C. § 1658 contains a two-year statute of limitations for securities claims that begins running when plaintiffs discover the facts constituting a securities violation. 28 U.S.C. § 1658(b)(1). In this case, the Court has already held that for the plaintiffs’ remaining claims to comply with the statute of limitations, the plaintiffs “must not have discovered the ‘facts constituting the violation’ before June 27, 2011.” *Medtronic*, 57 F. Supp. 3d at 978 (quoting 28 U.S.C. § 1658(b)(1)).

The discovery rule under Section 1658(b)(1) “begins to run once the plaintiff did discover or a reasonably diligent plaintiff would have discovered the facts constituting the violation – whichever comes first.” *Merck & Co. v. Reynolds*, 559 U.S. 633, 653 (2010) (internal quotation marks and alterations omitted). The Second Circuit has held that a “reasonably diligent plaintiff has not ‘discovered’ one of the facts constituting a securities fraud violation until he can plead that fact with sufficient detail and particularity to survive a 12(b)(6) motion to dismiss.” *City of Pontiac Gen. Emps. Ret. Sys. v. MBIA, Inc.*, 637 F.3d 169, 175 (2d Cir. 2011). In addition, the facts “need not

perfectly match the allegations that a plaintiff chooses to include in its complaint in order for the statute of limitations to run.” *Gavin/Solmonese LLC v. D’Arnaud-Taylor*, 68 F. Supp. 3d 530, 537 (S.D.N.Y. 2014).

#### **A. Count I False Statement Claim**

As to the remaining false statement claim in Count I – the claim that then-CEO Hawkins falsely stated on February 22, 2011 that he believed the product AMPLIFY would still receive FDA approval, despite receiving a letter before January 28, 2011 that indicated the FDA would not approve AMPLIFY, (Compl. ¶¶ 73-75, 79) – the Medtronic Defendants argue this claim is time-barred under the statute of limitations. They contend that by March 9, 2011, Medtronic made public in a Form 10-Q filing the truth about the FDA non-approval letter. (Compl. ¶ 82.) Thus, a plaintiff would have known at that point that a false statement had been made and consequently any complaint would have needed to be filed by March 9, 2013, before the complaint was filed in this case.

The plaintiffs argue that the defendants have waived this statute of limitations argument by failing to state it in their answer. While the plaintiffs concede that the defendants mentioned their statute of limitations defense as to the **scheme liability claims** in their answer, the plaintiffs contend that there is no mention of the statute of limitations defense as to the **false statement claims**. (See Am. Answer at 52, Dec. 3, 2014, Docket No. 85); *see also Wood v. Milyard*, 132 S. Ct. 1826, 1832 (2012) (“Ordinarily in civil litigation, a statutory time limitation is forfeited if not raised in a defendant’s answer or in an amendment thereto.” (internal quotation marks omitted)); *see*

*also United States v. Big D Enters., Inc.*, 184 F.3d 924, 935 (8<sup>th</sup> Cir. 1999) (“A defense based upon the statute of limitations is generally waived if not raised in a responsive pleading.”).

The Court concludes that the defendants sufficiently raised the statute of limitations defense in their answer. While the defendants do discuss the scheme liability claims in more detail when articulating the statutes of limitations and repose defenses in their answer, the answer also states, quite broadly, that “[t]he claims asserted in the Complaint are barred, in whole or in part, by the applicable statute of limitations and statute of repose.” (Am. Answer at 52.) That statement makes clear the defendants plan to assert statutes of limitations and repose defenses as to all claims. Moreover, courts have repeatedly recognized that a technical failure to plead a defense in an answer will not preclude the court from considering it if the plaintiff, as is the case here, has time to address the issue. *See, e.g., Ring v. Lexington Apartments & Motor Inns-Okla.*, 3 F. App’x 847, 851 (10<sup>th</sup> Cir. 2001).

The plaintiffs also argue that they deserve more time to conduct discovery and that this motion is, at a minimum, premature. But they offer little support for that argument. Indeed, the key case they cite is one in which reaching a decision on the motion for summary judgment required a fact-intensive inquiry that could not occur prior to the close of discovery. *See Weber v. The Travelers Home & Marine Ins. Co.*, No. 10-2142, 2011 WL 1757563, at \*1-\*2 (D. Minn. Mar. 1, 2011). Here, unlike in *Weber*, the facts are clear-cut and the Court can easily resolve the issue as a matter of law. The complaint clearly establishes that a plaintiff could have filed a complaint on this false statement

claim after March 9, 2011. (Compl. ¶ 82.) It is therefore unclear what specific additional facts the plaintiffs might uncover during discovery that would change the statute of limitations analysis as to this claim. Consequently, the Court finds that the remaining false statement claims are barred by the two-year statute of limitations and will grant the defendants' motion to dismiss the remainder claims of Count I.<sup>7</sup>

## **B. Count II Scheme Liability Claims**

The defendants argue that numerous prior news and academic articles, up through June 23, 2011, along with another lawsuit regarding INFUSE, the FDA's website, and initial inquiries from the Senate Finance Committee, made allegations and revealed facts

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<sup>7</sup> The Court is also unpersuaded by the argument that the defendants have waived the statute of limitations argument simply by not raising it at the motion-to-dismiss stage, or are estopped from raising it because it requires them to take positions that are inconsistent with their earlier positions in this case. The plaintiffs offers no controlling or compelling authority to support either argument. As to waiver, the plaintiffs cite *Thomas D. Wilson Consulting, Inc. v. Keeley & Sons, Inc.*, for example. No. 05-2115, 2006 WL 2788389 (E.D. Mo. Sept. 26, 2006). But that case is inapposite. The defendants in that case attempted to raise in a motion to dismiss a defense they neglected to raise in their answer. *Id.* at \*3-\*4. Such a maneuver clearly violates the Federal Rules of Civil Procedure and provides no guidance for the different procedural posture of this case. Here, the defendants did not raise the statute of limitations argument in their motion to dismiss, but did raise it in their answer and now properly address it at summary judgment. The estoppel argument also clearly fails. A defendant's framing of the facts or issues need not be identical at each stage of the litigation and in each motion the defendant argues.

The plaintiffs also argue that the defendants' summary judgment motion is akin to an improper motion for reconsideration, arguing that the Court already ruled on the timeliness of the plaintiffs' remaining claims. The Court rejects that argument. The Medtronic defendants included the statute of limitations defense in their answer, but expressly declined to argue that issue at the motion-to-dismiss stage. (*See* Am. Answer at 52); *Medtronic*, 57 F. Supp. 3d at 980. While the Court did conclude that the claims against the Consultant Defendants were timely, it did so based on allegations in the complaint, as is proper at the motion to dismiss stage. *Medtronic*, 57 F. Supp. 3d at 978 n.14. The Court's ruling did not preclude the Medtronic Defendants from raising this issue at summary judgment.

that would have allowed the plaintiffs to assert each element of a scheme liability claim much earlier. (*See, e.g.,* Bevilacqua Decl., Exs. 6-17.) In other words, even if the information available prior to June 23, 2011 would not have enabled the plaintiffs to make each and every individual allegation contained in their complaint, it easily would have allowed them to allege the elements of a scheme liability claim (deceptive acts, scienter, impact on the market, and causation), sufficient to survive a motion to dismiss. *Sitchting Pensioenfond ABP v. Countrywide Fin. Corp.*, 802 F. Supp. 2d 1125, 1137-38 (C.D. Cal. 2011) (citing *City of Pontiac* for the proposition that the statute of limitations “begins to run when a plaintiff has (or a reasonably diligent plaintiff should have) information and evidence sufficient to survive a motion to dismiss, not when a plaintiff has every conceivable fact that it will ultimately use to prove its case” (internal quotation marks omitted)); *id.* at 1135-39 (concluding that news reports and prior lawsuits would have been sufficient to make plaintiffs aware of problems with underwriting at Countrywide by early 2008); *see also Pension Trust Fund for Operating Eng’rs v. Mortg. Asset Sec. Transactions, Inc.*, 730 F.3d 263, 277-79 (3d Cir. 2013) (concluding that while a plaintiff could rely on a bank’s assurances regarding mortgage-backed securities, a lawsuit in in the fall of 2008 that alleged problems with those securities would have caused a reasonable investor to start investigating and the limitations period began running at that point). As a result, since the complaint filed on June 27, 2013 was filed more than two years after June 23, 2011, and even longer after many of the articles cited by the defendants, the defendants argue it is time-barred by the applicable statute of limitations. 28 U.S.C. § 1658(b)(1).

After reviewing the defendants’ argument, and the myriad sources both sets of parties provide, the Court concludes that the plaintiffs had “sufficient information,” prior to June 27, 2011, to adequately plead their scheme or course of conduct liability count. *City of Pontiac*, 637 F.3d at 175. As the defendants exhaustively document, a variety of sources prior to the June 28, 2011 Spine Journal issue offer information that could support each element of the plaintiffs’ claims. For example, several sources establish the deceptive acts alleged by the plaintiffs – paying money to physicians; scientific articles failing to address adverse events in INFUSE’s development; and scientific articles overstating the benefits of INFUSE and overstating the disadvantages of other methods, products, and procedures. (*See, e.g.*, Bevilacqua Decl., Ex. 11 (New York Times article noting that studies on INFUSE had hidden adverse effects of the drug and that the doctors responsible for those studies received millions in compensation from Medtronic); Compl. ¶ 83 (describing an April 11, 2011 New York Times article that reported that some doctors had overstated the benefits of INFUSE).)

As for scienter – that the alleged scheme “was intended to, and did, drive sales of INFUSE and with it, Medtronic’s profits and share price,” (Compl. ¶ 165), – the May 25, 2011 Spine Journal article by Eugene Carragee, along with subsequent news articles, showcase early revelations of Medtronic’s drive to dominate the marketplace with INFUSE. (Compl., Ex. G; Bevilacqua Decl., Ex. 12, 14-15.) Finally, the *Minneapolis Firefighters* litigation, which targeted Medtronic’s payment to doctors seeking to promote off-label uses of INFUSE, is an early source that shows both the scheme’s impact on the market (i.e., the unjustified faith Medtronic investors had in INFUSE

revenues) and loss causation (i.e., truth about INFUSE reducing Medtronic's share price).<sup>8</sup> (*Minneapolis Firefighters* Compl. ¶ 3-9, 245, 286-87, 304-05.) Moreover, financial analysis cited by the plaintiffs after the June 28, 2011 Spine Journal issue clarified that the new Spine Journal issue would simply continue to dampen INFUSE sales, not provide an unexpected or unforeseen freefall in sales or share prices. (Wood Decl., Ex. 29.)

Although the plaintiffs advance several arguments in response to the defendants' motion for summary judgment on this issue, the briefing and oral argument in this case make plain that this issue effectively boils down to the importance to the plaintiffs' complaint of Medtronic's editing, designing, and ghostwriting of research and publications related to INFUSE.<sup>9</sup> Indeed, the plaintiffs effectively concede as much in their declaration, acknowledging that the only fact that is missing from pre-June 27, 2011 sources is that Medtronic designed and edited INFUSE studies and articles. (Wood Decl., Ex. 24.)

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<sup>8</sup> Given the similarities between the allegations in these two cases – one alleging that Medtronic paid and colluded with physicians to buoy on-label sales of INFUSE, the other alleging that Medtronic paid and colluded with physicians to boost off-label sales of INFUSE – the Court finds that the on-label/off-label distinction is not so great that the *Minneapolis Firefighters* litigation could not put the plaintiffs on notice as to some aspects of their claims. *Gavin/Solmonese LLC*, 68 F. Supp. 3d at 537 (“Facts need not perfectly match the allegations that a plaintiff chooses to include in its complaint in order for the statute of limitations to run.”) Similarly, that the *Minneapolis Firefighters* plaintiffs did not allege scheme liability does not mean that their allegations could not still inform a later scheme liability claim by different plaintiffs.

<sup>9</sup> As discussed above in more detail, the Court rejects the plaintiffs' arguments that the defendants have waived a timeliness defense, or are estopped from raising it. The Court also rejects the plaintiffs' contention that more record development is required before the Court can decide the timeliness issue.

The Court previously recognized the importance of Medtronic's decision to edit and ghostwrite INFUSE studies. In its prior Order, the Court noted that the plaintiffs' scheme liability theory "is that Defendants' actions in manipulating the [INFUSE] studies . . . – had the effect of artificially propping up Medtronic stock prices on account of confidence in INFUSE sales." *Medtronic*, 57 F. Supp. 3d at 981. The Court also stated that the plaintiffs' "scheme allegations center on the concerted manipulation of studies **between** Medtronic and the physician consultants." *Id.* at 978 n.14. Indeed, in summarizing the plaintiffs' allegations, the Court noted that the plaintiffs did not just focus on Medtronic's payments to physicians, but also alleged "that Medtronic personnel edited journal articles by [Medtronic's] physician consultants." *Id.* at 977 (citing Compl. ¶¶ 17, 163.). Nevertheless, as already noted, the Court was only considering the plaintiffs' allegations under the motion-to-dismiss standard in its prior Order. Moreover, although the explicit reference to editing and ghostwriting did not arise until the October 2012 release of the Senate Report, allegations of manipulation are apparent in the myriad news article, and other sources, detailing the financial relationships tying Medtronic to its physician consultants. Indeed, in a June 21, 2011 news article, Carragee went so far as to allege, effectively, editing, design, and ghostwriting on the part of Medtronic. (Bevilacqua Decl., Ex. 12 at 3-5 ("There has been a corrosive suspicion surrounding researchers' financial ties to Medtronic, **possible company influence on data presentation** and the basic safety reporting by some industry-sponsored surgeons." (emphasis added)).)

It is true that allegations of editing and ghostwriting were most obvious in the Senate Report. That report found, for instance, that “Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees.” (Compl. ¶ 125.) The report also revealed that “Medtronic officials inserted language into studies that promoted INFUSE as a better technique than” an alternative method. (*Id.*)

The problem with that argument is, however, that the October 2012 Senate Report falls outside the class period and, to the extent allegations of editing and ghostwriting are critical claims of deceptive acts on Medtronic’s part, they are not tied to any actual loss (i.e., drop in stock). Indeed, the complaint lists ghostwriting and editing in the loss causation subsection, but does not actually list any loss occurring beyond August 2011, much less after the release of the Senate Report. (*See id.* ¶¶ 136-45 (alleging that loss was caused by Medtronic’s drafting and editing of INFUSE studies but only alleging drops in stock prices in March through August of 2011, not after the release of the Senate Report).) As a result, the Court will not rely on the Senate Report as the trigger date for the statute of limitations.<sup>10</sup> *See Loos v. Immersion Corp.*, 762 F.3d 880, 890 (9<sup>th</sup> Cir.

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<sup>10</sup> Because of this conclusion, the Court is not persuaded by the plaintiffs’ citation to *Intesa Sanpaolo, S.p.A. v. Credit Agricole Corp. & Inv. Bank*, 924 F. Supp. 2d 528, 535-36 (S.D.N.Y. 2013). In that case, critical facts were revealed through the defendants’ emails; as a result, the existence of some wrongdoing in earlier publicly available sources did not trigger the statute of limitations. *Id.* Here, the allegations in the complaint – aside from the specific allegations about ghostwriting and editing that came from the Senate Report but are not tied to harm – are all supported by publicly available information.

2014) (rejecting plaintiff's reliance, as to loss causation, on two post-class period disclosures because the impact of those disclosures on the defendant company's stock price was not alleged in the complaint).

Even if the Court were to overlook the fact that the defendants have not tied loss to their allegations of ghostwriting and editing, and have not shown any loss that followed the release of the Senate Report, the record shows that the facts contained in the Senate Report, and certainly the facts contained in the June 28, 2011 Spine Journal issue, are not so different than the facts available prior to June 27, 2011 that the plaintiffs could not have filed an earlier complaint and survived a motion to dismiss. Reporting on significant payments to doctors and allegations by Carragee that Medtronic was influencing data presentation are close to what was eventually revealed in the Senate Report. *Gavin/Solmonese LLC*, 68 F. Supp. 3d at 537. And the June 28, 2011 Spine Journal issue does not, alone, offer any significant new revelations. (See Wood Decl., Ex. 24.) While articles and editorials in that issue did discuss, in more detail than before, alleged collusion between industry and physicians generally, and flawed methodology on the part of INFUSE studies specifically, it did not represent the dramatic revelation that the plaintiffs make it out to be. (June 2011 Spine Journal Editorial at 22; Compl. ¶¶ 104, 106, 108; Wood Decl., Ex. 28.) Contrary to the plaintiffs' assertions, previous articles – most obviously the Carragee quote in the June 21, 2011 Milwaukee Journal Sentinel article – did not simply reveal physician bias, but explicitly explored and alleged manipulation and collusion. (Bevilacqua Decl., Ex. 12 at 3-5.)

Finally, to the extent the plaintiffs now claim that the Senate Report should still be considered because its revelations are critical for proving Medtronic's scienter, the Court finds otherwise. As to scienter, the plaintiffs explicitly allege that the "scheme and course of conduct . . . was intended to, and did, drive sales of INFUSE and with it, Medtronic's profits and share price." (Compl. ¶ 165.) The Court recognized this construction of scienter in its prior Order, holding that, "[i]n light of Medtronic's allegations that its goal was to make INFUSE the standard of care for bone growth and the need for clinical studies emphasizing its effectiveness without side effects, these allegations give rise to a strong inference of scienter." *Medtronic*, 57 F. Supp. 3d at 983 (citing paragraphs in the complaint discussing the May 25, 2011 and June 28, 2011 Spine Journal issues). The Senate Report is not necessary to survive a motion to dismiss as to scienter.

In sum, as the preceding discussion demonstrates, the plaintiffs had access to sufficient public information (i.e., discovered the facts constituting the violation) prior to June 27, 2011 to survive a motion to dismiss on their scheme liability claims. *See Stichting Pensioenfonds ABP*, 802 F. Supp. 2d at 1137-38. As a result, the Court will grant the defendants' motion for summary judgment on the plaintiffs' remaining scheme liability claims and dismiss Count II.<sup>11</sup> *See 100079 Canada, Inc. v. Stiefel Labs., Inc.*, 596 F. App'x 744, 749 (11<sup>th</sup> Cir. 2014) (dismissing at the summary judgment stage a

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<sup>11</sup> As a result of the Court's decision on the statute of limitations issue, it need not reach the defendants' statute of repose argument.

securities fraud claim because the plaintiff had sufficient knowledge to plead his claim more than two years before he filed it).

#### **IV. ADDITIONAL ISSUES**

The plaintiffs also assert control person claims in Count III. Because control person liability under Section 20 of the Exchange Act is derivative of other claims under the Exchange Act, *Medtronic*, 57 F. Supp. 3d at 984, and because the Court will dismiss the plaintiffs' remaining claims under Counts I and II, the Court will also dismiss the plaintiffs' control person claims.

Additionally, in response to an order on discovery matters by United States Magistrate Judge Franklin L. Noel, (Order, June 12, 2015, Docket No. 144), the defendants have submitted an objection, (Obj. to Magistrate Judge's Order, June 29, 2015, Docket No. 148.). Because the Court has granted the defendants' motion for summary judgment in full, the defendants' objections are now moot. Consequently, the Court will deny them. In addition, the Court will also deny the plaintiffs' outstanding motion for class certification as moot.

#### **ORDER**

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

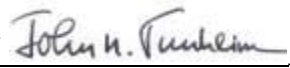
1. The defendants' Motion for Summary Judgment [Docket No. 88] is **GRANTED**. The plaintiffs' remaining claims in Counts I, II, and III are **dismissed with prejudice**.

2. The defendants' Appeal/Objection to the Magistrate Judge's Order [Docket No. 148] is **DENIED as moot**.

3. The plaintiffs' Motion to Certify Class, Appoint Class Representatives, and Appoint Class Counsel [Docket No. 108] is **DENIED as moot**.

**LET JUDGMENT BE ENTERED ACCORDINGLY.**

DATED: September 30, 2015  
at Minneapolis, Minnesota.

s/   
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JOHN R. TUNHEIM  
Chief Judge  
United States District Court